K123099

510(k) Summary

Submitter's Identifications:
Manufacturer and Sponsor:
Avazzia, Inc.
13140 Coit Road., Suite 515
Dallas, TX 75240 USA
Establishment Registration # 3004839404
Official Contact Person: Tammy Lahutsky
Date of Summary Preparation: April 2014

MAY 2 3 2014

Classifications: TENS, Class II 21 CFR 882.5890 GZJ

Information of the 510(k) Cleared Devices (Predicate Device):
Body-Stim™, Biomodulator™, Best-RSI™, Best-Pro 1™, Model BEST – AV1™, (K062641) 4/30/2007, TENS, Class II 21 CFR 882.5890 GZJ

Intended Use:
Pro-Sport™ is indicated for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain

Trade Names of Candidate Devices: Best AV2 Pro Sport™ Device

Description of Candidate Devices:
Description of Candidate Devices as might be found in the labeling or promotional material:
The candidate Pro-Sport Avazzia device is a micro-current transcutaneous electro-stimulation device. It is an easy-to-use, handheld, AA battery-operated portable device for use in the home or clinic.

Description of the Candidate Devices – How the devices work:
The device is a portable, battery operated microcurrent electrical stimulation device that applies charge and power to the tissue through electrodes where maximum power delivered to the load is controlled and limited, and an automatic shut off is implemented.

The user can passively place the electrodes where indicated and apply stimulation for a period of time.

The user controls the output by selecting the preset mode and power setting. The device's controls and visual indicators are located on the upper side of the case and on the upper cover.

The Best-Pro 1™, Best-RSI™, Biomodulator™, Body-Stim™ devices have 4 pre-set modes.

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The Pro-Sport™ device incorporates a more sophisticated digital liquid crystal display user interface to help the user select the mode and see parameters like the power level, time, and other information and has one mode that allows practitioners to set up their own therapy signals.

Scientific Concepts that form the basis of the devices:
Various modes in the candidate device are suited for TENS applications.

Design Description: Significant physical and performance characteristics of the device including stimulation output specifications & Summary of the Technological Characteristics Compared to the Predicates are shown below:

Discussion of any different technological characteristics between the devices and the predicate devices:

The candidate device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device as summarized in the table of the technological characteristics.

The differences between the candidate device and the predicate device are:

- the Pro-Sport user-interface implements a menu system that allows the user to select from a list of preset modes beyond the 4 modes in the predicate devices
- the Pro-Sport AVA mode allows the stimulation parameters to be programmed by the user
- the Pro-Sport displays values in a digital display format instead of an LED that represents a range of values which allows values to be displayed in smaller incremental values

Summary of Technical Characteristics (i.e., design, material, chemical composition, energy source)		
Parameter	**Avazzia Candidate Device**	**Predicate Devices**
Labeling Claims Indication for Use See Note 1	TENS	TENS
Device Name and Model	Avazzia Pro Sport™	Best-Pro 1, Best-RSI, Biomodulator, and Body Stim
510(k) Number	K123099	K062641
Manufacturer	Avazzia, Inc.	Avazzia, Inc.
Power Source(s): Number, Size and Type of Batteries	2 – 1.5 V AA batteries	2 – 1.5 V AA batteries
Number of Output Modes	24	4 models = 4
Low Battery indication?	Yes	Yes
Timer Range (minutes)	60 minutes	60 minutes
Compliance with Voluntary Standards?	Yes	Yes

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Summary of Technical Characteristics (i.e., design, material, chemical composition, energy source)		
Parameter	**Avazzia Candidate Device**	**Predicate Devices**
Compliance with 21 CFR 898?	Yes	Yes
Weight (lbs., oz.)	7oz	7oz
Dimensions (in.) [W x H x D]	2.6" X 1.35" X 4.7"	2.6" X 1.35" X 4.7"
Housing Materials and Construction	Handheld ABS plastic housing with a Polypac plastic nameplate and onboard electrodes	Handheld ABS plastic housing with a Polypac plastic nameplate and onboard electrodes
User Interface Display	LCD	LEDs
Design material	PCBs inside plastic case housing	PCBs inside plastic case housing
Energy type	Electro-stimulation	Electro-stimulation

Stimulation Output Specifications		
	Avazzia Candidate Device	**Predicate Devices**
Pulse Duration	0.1 – 1.15 mS	0.1 – 1.15 mS
Pulse Frequency	0.5 to 2500 Hz	0.5 to 2500 Hz
Output Voltage	20 – 650 V	20 – 650 V
Current Amplitude TENS	0 – 90mA	0 – 90mA
Timeout	60 minutes	60 minutes
Waveform	Pulsed, damped, asymmetric biphasic sinusoidal	Pulsed, damped, asymmetric biphasic sinusoidal
Number of modes of stimulation	14 preset modes including AVA user programmable mode	4 preset modes

Summary of how the technological characteristics of your device compare to the predicate device:

- *Do the candidate Devices have the same indications for use?* Yes
- *Do the candidate Devices have the same Technological Characteristics?* Yes
- *Do the candidate devices pose any new questions regarding safety of effectiveness?* No
- *Do the candidate devices have accepted scientific methods for evaluating safety and effectiveness?* Yes
- *Do the candidate devices demonstrate no diminishment of performance?* Yes

The Avazzia device technological specifications are the same; therefore, differences in user interface do not pose new questions regarding safety and effectiveness.

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Conclusions:
The devices have intended uses and technological characteristics that are substantially equivalent to the predicate devices Body-Stim™, Biomodulator™, Best-RSI™, Best-Pro 1™, Model BEST – AV1™ (K062641), since their purpose, application, mechanism of action, utilized materials, basic technical characteristics, functionality and manufacturing processes are similar. Verification and validation tests as well as certificates and test reports contained in this submission demonstrate that the submitted models are substantially equivalent to the safety and effectiveness as that of the cleared devices.

Accessories

Self-adhesive conductive electrode pads
Finger electrode
Cutaneous electrodes
Soft tissue electrodes – Y electrodes
Comb electrode
Small Circular Electrode: Common name: Pencil electrode
Lead wires

The software verification is conducted according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff – May 11, 2005.

The four candidates devices and accessories meet safety requirements IEC 60601-1 and requirements EMC:IEC 60601-1-2.

Conclusions:
The device has intended uses and technological characteristics that are substantially equivalent to the predicate devices Body-Stim™, Biomodulator™, Best-RSI™, Best-Pro 1™, Model BEST – AV1™ (K062641).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 23, 2014

Avazzia, Inc.
c/o Tammy Lahutsky
Regulatory Affairs
13140 Coit Road, Suite 515
Dallas, TX 75240

Re: K123099
Trade Name: Best AV2 Pro-Sport™
Regulation Number: 21 CFR 882.5950
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: May 14, 2014
Received: May 16, 2014

Dear Ms. Lahutsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K123099

Device Name
Best AV2 Pro Sport™ Device

Indications for Use *(Describe)*
- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.05.23 09:42:33 -04'00'

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